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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,230	08/17/2006	Thorsten Bechert	WFG-39710	7580

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EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

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11/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,230	BECHERT ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-72* is/are pending in the application.

4a) Of the above claim(s) *51-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-50,71 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 09/17/2010.

- Claims 71-72 have been added.
- Claims 32-72 are pending in the instant application.
- Claims 51-70 have been previously withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-45, 47-50 rejected under 35 U.S.C. 102(b) as being anticipated by BECHERT et al (WO 02/17984; wherein US 6,984,392 is used as a translation) **are maintained** for reasons of record in the previous office action filed on 06/21/2010 and as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-50, 71-72 rejected under 35 U.S.C. 103(a) as being unpatentable over BECHERT et al (WO 02/17984; wherein US 6,984,392 is used as a translation) in view of HANKE et al (US 6,720,006) **are maintained** for reasons of record in the previous office action filed on 06/21/2010 and as discussed below.

Response to Arguments

Applicant argues that Bechert does not disclose a body care product for application to skin and/or mucosa as acknowledged by the Examiner. Bechert fails to teach each and every limitation of claim 32 and therefore Bechert can not anticipate such claim or the claims that depend therefrom.

The Examiner finds this argument unpersuasive, because the Examiner only acknowledged that BECHERT does not disclose explicitly a composition in a cream form. However, BECHERT does disclose a body care product for application to skin and/or mucosa, since the phrase “body care product” has a broader scope than cream. For instance, Applicant’s specification states that "body care products are products which are brought into contact with the human or animal skin and/or mucosa in order to achieve a cleaning, protective, therapeutic, healing, caring, cosmetic or alleviating effect”, such as “medical bandages” (see specification at pg. 3, line 18-29), wherein BERCHERT teaches the composition can be coated on medical devices, such as catheter or intratracheal tubes, which a product in contact with the skin and mucosa in order to achieve a cleaning, protective, therapeutic, healing, caring and alleviating effect

Additionally, the recitation "body care product" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this case, BECHERT's composition can be capable of applying to the body.

Applicant argues that there is no basis for the proposed combination of teachings.

The Examiner finds this argument unpersuasive, because as discussed in the previous office action, the cream form composition would be able to treat skin infection, and reasonably would have expected success because silver particles were know to be in cream form and incorporated into medical components in the prior art.

Applicant argues that the incorporation of Bechert's aggregates in a body product such as a cream would destroy the basis of the Bechert invention. The aggregate matrix formed implants and coatings contemplated by Bechert do not extend to incorporation of aggregates in creams, and therefore, the proposed modification is improper. A combination of references, where the invention of the reference would be destroyed for its intended purpose, is improper.

The Examiner finds this argument unpersuasive, because the basis of the BECHERT's invention is the antimicrobial material for implanting in bones and for

coating (see abstract), wherein a cream form would allow the antimicrobial material to be coated on the body or coated on medical bandages and medical devices. Antimicrobial creams are well known in the art.

Applicant argues that neither reference teaches a treatment of an infection, but rather, each discloses prophylaxis treatments for prevention of infection. Moreover, Hanke basis his invention on the use of nanoparticles and one skilled in the art would not be led to modify Bechert contrary to the Hanke teachings. The porous aggregates of specified particle size and porosity do not suggest combination in cream for treatment of infection. The teaching in Bechert is that the aggregates of silver particles in the matrix material prevent the growth of microorganisms in the material, such that the implanted material does not become the source of microorganisms that may cause infection of the patient. That is, Bechert is directed to preventing infection in implants and the like, not treating infection by means of a body care product for application to skin and/or mucosa. Bechert does not disclose a method of treatment of the patient, but only a method to keep the material to be implanted free of microorganisms. This prophylaxis teaching does not suggest a composition useful for the treatment of an existing infection. Hanke teaches a prophylaxis treatment particularly based on the use of nanoparticles to prevent discoloration of the skin. Accordingly, there is no suggestion to one skilled in the art to use the significantly larger particles in Bechert to provide a body care product such as a cream to treat infection. Such a conclusion may only be based on applicants' own teachings.

The Examiner finds this argument unpersuasive, because HANKE teaches "it is already known as well to use silver in various forms as anti-microbial agent; however, it is a serious problem to find the most appropriate delivery system. For example there have been numerous attempts incorporate silver into various polymer articles, such as pipes, medical devices....medical catheters" (see col. 1, line 41-62) and body care products, such as cream (see col. 1, line 16-31). Thus, one of ordinary skilled would obviously use anti-microbial agents in catheters and body care products, because it would provide more industrial use of the anti-microbial agent.

Applicant argues that the particle size of 1 to 50 nm is an essential feature of the body care products in Hanke. As noted above, Hanke teaches there is no discoloration of the skin due to the small particle size (column 5, lines 34-36). This teaching specifically teaches away from increasing the size of the particles by replacing the silver nanoparticles in Hanke with the very significantly larger particles from Bechert. Second, there is no practical motivation for using the aggregates of Bechert in Hankers prophylaxis cream composition since with the aggregates are more expensive to make and are not known to have any advantages nor to even provide an infection treatment activity. Thus, aside from applicants' own teachings, there is no prior art knowledge suggesting the Bechert prophylaxis would be useful in the treatment of existing infection, and such is certainly not provided by Hankers preference for nanoparticles.

The disparity of the teachings in Bechert and Hanke and the unobviousness of their combination, are further demonstrated by the fact that the aggregates and silver particles in Bechert are unable to penetrate the skin and the mucosa. In contrast,

nanoparticles demonstrate such penetration of the skin and mucosa. Accordingly, one skilled in the art would not expect the incorporation of the Bechert aggregates in the Hanke cream to provide similar results. In fact, the knowledge of one skilled in the art makes unlikely any reliable prediction of the properties of the cream resulting from the combination of the teachings.

The Examiner finds this argument unpersuasive, because as discussed above, HANKE is used as a secondary reference to show that the prior art had known to use silver particles as antimicrobial agents in medical devices, such as catheters, and body care products, such as cream.

Applicant argues that Bechert and Hanke contemplate prophylaxis treatment, not treatment of an existing infection. Thus, the result is not known and the composition can not be optimized if the result is not known. In the absence of a prior art teaching of the claimed porous particles in a body care product for application to skin, there is no result effective variable to enable optimization of particle size and amounts.

The Examiner finds this argument unpersuasive, because Applicant's claims are directed to a composition and not to the treatment of an existing infection. Additionally, Applicant's porous particles are silver particles, wherein the prior art had known to use silver particles as anti-microbial agents; thus, it would have been obvious to optimize the effect of the anti-microbial agent.

Applicant argues that the difference in size between the Bechert and Hanke particles is so great that it cannot be assumed to be an obvious interchange or modification. Specifically, the Hanke nanoparticles are increased by a factor of 20 to

100,000 (20 x 50 nm = 1 micron, 100,000 x 1 nm = 100 micron.) Moreover, even if one skilled in the art were to consider increasing the size of the particles in Hanke, there is no suggestion of the porous particles taught in Bechert. There is no motivation or explanation for one skilled in the art to assume that the porous particles in Bechert may be substituted in the non-porous nanoparticle composition of Hanke. The substantial difference in particle size has been found to be completely unable to penetrate the skin and mucosa in the topical applications of the present invention. The prior art certainly provides no explanation for the effect to result from such a property difference. Further, the commonality of silver metal is not sufficient to lead one skilled in the art to assume the Hanke cream will work with the Bechert aggregates. That is, there is an association of property with particle size as described in the attached article by Auffan et al., Nature Nanotechnology, Vol. 4, 2009, 634-641, Towards a definition of inorganic nanoparticles from an environmental, health and s a f e t y perspective. As described by the authors, silver particles of 15, 30 and 55 nm size are cytotoxic. As particularly disclosed at page 638, right column, last paragraph and Fig. 4, the 30 nm and 15 nm silver nanoparticles are more toxic than the 55 nm silver nanoparticles. Meanwhile, toxicity of nanoparticles is discussed, e.g., due to catalytic properties, a size dependent generation of ROS (reactive oxygen species) and an enhanced absorption capacity (see conclusion, last paragraph of the Auffan et al. publication). Such nanospecific effects are not associated with the structure of the claimed aggregates.

The Examiner finds this argument unpersuasive, because the particle sin BECHERT and HANKE are both silver particles and the prior art had known that silver

particles are used as anti-microbial agents; thus, there is motivation use what the prior art teaches and that is to use silver anti-microbial particles to coat catheters or as an anti-microbial cream.

Applicant argues that unexpectedly, the porous particles enable an anti-inflammatory effect in the body care products at a much lower concentration than with non-porous particles of the same size. The porous particles of the claimed body care products also result in a more stable distribution of particles within the carrier materials of the type used with creams. The stability of the distribution also enables the use of lower viscosity preparations. None of these advantages is suggested or contemplated by the prior art.

The Examiner finds this argument unpersuasive, because the prior art uses the same silver particle as claimed by Applicant; thus, the anti-inflammatory effect would have inherently resulted with the prior art's composition.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618